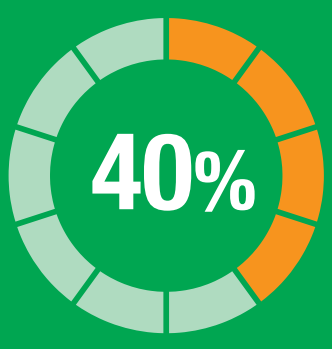
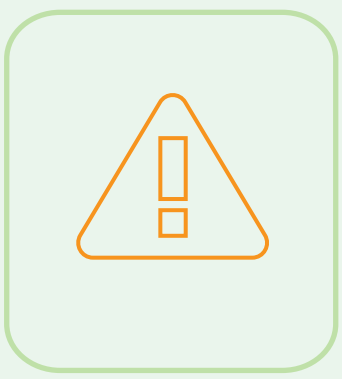
5 WAYS
REGULATORY DATA CAN DRIVE PERFORMANCE

In a recent survey of senior regulatory executives and quality professionals, 40% of respondents reported seeing positive results in their earnings and profits over a five-year period due to Regulatory and quality performance initiatives.



The key to driving performance is access to complete, accurate and meaningful data. Regulatory departments that can structure relevant data to create meaningful insights can directly impact operational efficiency, speed to market and many other areas.

Below are 5 ways regulatory teams can use data to drive performance:

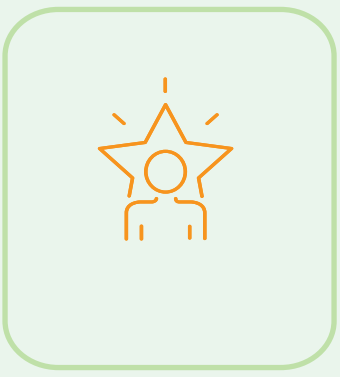


Limit risk and recalls

Device manufacturers that take a more proactive approach to quality can reduce risks, including the risk of recalls. Many leading manufacturers accomplish this by closely monitoring first time right percentage the ability to complete every step of their registration processes right the first time. This approach extends out to their suppliers and other business partners as well.

Improved, patient outcomes and customer satisfaction

The benefits of a culture of quality are far reaching. When a product reaches patients on time, outcomes are improved and satisfaction among customers (clinicians, consumers) is higher. When questioned on their driver for improvement initiatives, two-thirds of senior regulatory executives and quality professionals report that it is customer demand.

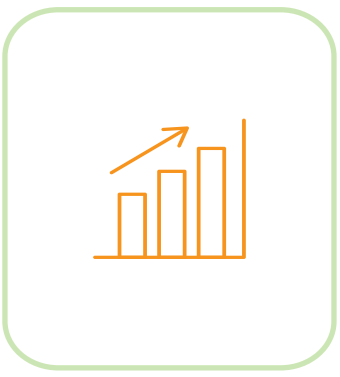


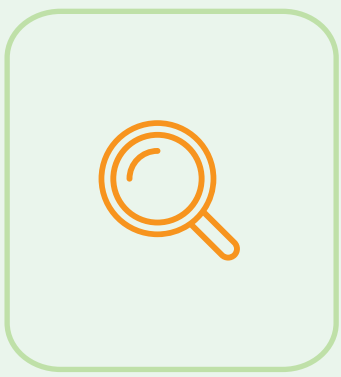
Drive operational excellence

The infusion of right planning throughout people, processes, products and technologies drives overall operational excellence. It can result in reduced cycle times, cost savings, increased margins and additional performance-oriented outcomes. Nearly half (47%) of senior regulatory executives and quality professionals surveyed report that their regulatory efforts have increased profitability. Regulatory data can be used to optimize systems and processes to drive operational excellence.

Accelerate time to market

According to the Tufts Center for the Study of Drug Development, the average cost to develop and gain marketing approval for a new drug is $2.558 billion. Improving overall regulatory management can reduce errors and related setbacks during the drug development cycle, enabling a manufacturer to deliver its product to market sooner. Cutting the cycle time down by even a month could potentially increase market share and revenue.





Meet compliance requirements

Even though the FDA and other regulators have placed an increased emphasis on pharmaceutical quality, manufacturers still have to ensure compliance with new and emerging regulations. Compliance has not gone away; rather it has been coupled with quality. Manufacturers can leverage highly efficient regulatory management systems and quality metrics to achieve proactive compliance and thereby reduce regulatory scrutiny.

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